

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

IN RE: DIET DRUGS (PHENTERMINE/
FENFLURAMINE/DEXFENFLURAMINE)
PRODUCTS LIABILITY LITIGATION

THIS DOCUMENT RELATES TO:

SHEILA BROWN, et al.

v.

AMERICAN HOME PRODUCTS
CORPORATION

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) MDL NO. 1203
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) CIVIL ACTION NO. 99-20593
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) 2:16 MD 1203
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MEMORANDUM IN SUPPORT OF SEPARATE PRETRIAL ORDER NO. 8429

Bartle, C.J.

March 15, 2010

Sherri L. Brown ("Ms. Brown" or "claimant"), a class member under the Diet Drug Nationwide Class Action Settlement Agreement ("Settlement Agreement") with Wyeth,¹ seeks benefits from the AHP Settlement Trust ("Trust"). Based on the record developed in the show cause process, we must determine whether claimant has demonstrated a reasonable medical basis to support her claim for Matrix Compensation Benefits ("Matrix Benefits").²

1. Prior to March 11, 2002, Wyeth was known as American Home Products Corporation.

2. Matrix Benefits are paid according to two benefit matrices (Matrix "A" and Matrix "B"), which generally classify claimants for compensation purposes based upon the severity of their medical conditions, their ages when they are diagnosed, and the presence of other medical conditions that also may have caused or contributed to a claimant's valvular heart disease ("VHD"). See Settlement Agreement §§ IV.B.2.b. & IV.B.2.d.(1)-(2). Matrix A-1 describes the compensation available to Diet Drug Recipients with

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To seek Matrix Benefits, a claimant must first submit a completed Green Form to the Trust. The Green Form consists of three parts. The claimant or the claimant's representative completes Part I of the Green Form. Part II is completed by the claimant's attesting physician, who must answer a series of questions concerning the claimant's medical condition that correlate to the Matrix criteria set forth in the Settlement Agreement. Finally, claimant's attorney must complete Part III if claimant is represented.

In March, 2004, claimant submitted a completed Green Form to the Trust signed by her attesting physician, Khawaja N. Anwar, M.D., F.A.C.C., F.C.C.P. Based on an echocardiogram dated August 22, 2002, Dr. Anwar attested in Part II of Ms. Brown's Green Form that she suffered from moderate mitral regurgitation, an abnormal left ventricular end-systolic dimension, and a reduced ejection fraction in the range of 40% to 49%. Based on such findings, claimant would be entitled to Matrix A-1, Level II benefits in the amount of \$661,718.³

2. (...continued)

serious VHD who took the drugs for 61 days or longer and who did not have any of the alternative causes of VHD that made the B matrices applicable. In contrast, Matrix B-1 outlines the compensation available to Diet Drug Recipients with serious VHD who were registered as having only mild mitral regurgitation by the close of the Screening Period or who took the drugs for 60 days or less or who had factors that would make it difficult for them to prove that their VHD was caused solely by the use of these diet drugs.

3. Under the Settlement Agreement, a claimant is entitled to
(continued...)

In the report of claimant's echocardiogram, Dr. Anwar noted that claimant had "+1 [mitral regurgitation]." Under the definition set forth in the Settlement Agreement, moderate or greater mitral regurgitation is present where the Regurgitant Jet Area ("RJA") in any apical view is equal to or greater than 20% of the Left Atrial Area ("LAA"). See Settlement Agreement § I.22. Dr. Anwar also observed that claimant had an ejection fraction ">60%." An ejection fraction is considered reduced for purposes of a mitral valve claim if it is measured as less than or equal to 60%. See id. § IV.B.2.c.(2)(b)iv). Finally, Dr. Anwar found that claimant had "[n]ormal [left ventricular] size & systolic function." A left ventricular end-systolic dimension is considered abnormal if it is measured as greater than or equal to 45 mm by M-mode or 2-D echocardiogram. See id. § IV.B.2.c.(2)(b)iii).

In July, 2005, the Trust forwarded the claim for review by Jeffrey S. Soble, M.D., F.A.C.C., one of its auditing cardiologists. In audit, Dr. Soble concluded that there was no reasonable medical basis for Dr. Anwar's finding that claimant had moderate mitral regurgitation. In support of this conclusion, Dr. Soble explained that claimant had "[b]orderline

3. (...continued)

Level II benefits for damage to the mitral valve if he or she is diagnosed with moderate or severe mitral regurgitation and one of five complicating factors delineated in the Settlement Agreement. See Settlement Agreement § IV.B.2.c.(2)(b). A reduced ejection fraction and an abnormal left ventricular end-systolic dimension are each one of the complicating factors needed to qualify for a Level II claim.

jet duration; RJA/LAA=11%." Dr. Soble also concluded that there was no reasonable medical basis for the attesting physician's finding of a reduced ejection fraction because claimant's "[ejection fraction] is normal" and in the range of 65% to 70%.⁴

Based on the auditing cardiologist's findings, the Trust issued a post-audit determination denying Ms. Brown's claim. Pursuant to the Rules for the Audit of Matrix Compensation Claims ("Audit Rules"), claimant contested this adverse determination.⁵ In her initial contest submission, claimant argued that she is "very confident there's valid cause for the evaluation of the attesting physician." Claimant also noted that she "submitted all the required documents by the timeline of the [T]rust" and "waited a very long time for a fair answer." Claimant subsequently submitted an additional letter wherein she contended that she should prevail on her claim because the attesting physician found moderate mitral regurgitation and a reduced ejection fraction. Claimant also stated that she was unable to submit a verified statement of

4. Dr. Soble also noted that claimant did not have an abnormal left ventricular end-systolic dimension. However, Dr. Soble did not determine, and the Trust did not argue, that Dr. Anwar's representation that claimant had an abnormal left ventricular end-systolic dimension lacked a reasonable medical basis.

5. Claims placed into audit on or before December 1, 2002 are governed by the Policies and Procedures for Audit and Disposition of Matrix Compensation Claims in Audit, as approved in Pretrial Order ("PTO") No. 2457 (May 31, 2002). Claims placed into audit after December 1, 2002 are governed by the Audit Rules, as approved in PTO No. 2807 (Mar. 26, 2003). There is no dispute that the Audit Rules contained in PTO No. 2807 apply to Ms. Brown's claim.

another medical expert because the cardiologists in her area were not accepting Diet Drug claimants.

The Trust then issued a final post-audit determination, again denying Ms. Brown's claim. Claimant disputed this final determination and requested that the claim proceed to the show cause process established in the Settlement Agreement. See Settlement Agreement § VI.E.7.; PTO No. 2807, Audit Rule 18(c). The Trust then applied to the court for issuance of an Order to show cause why Ms. Brown's claim should be paid. On February 28, 2006, we issued an Order to show cause and referred the matter to the Special Master for further proceedings. See PTO No. 6028 (Feb. 28, 2006).

Once the matter was referred to the Special Master, the Trust submitted its statement of the case and supporting documentation. Claimant then served a response upon the Special Master. The Trust submitted a reply on May 5, 2006. The Show Cause Record is now before the court for final determination. See Audit Rule 35.

The issue presented for resolution of this claim is whether claimant has met her burden in proving that there is a reasonable medical basis for the attesting physician's findings that she had moderate mitral regurgitation and a reduced ejection fraction. See id. Rule 24. Ultimately, if we determine that there is no reasonable medical basis for the answers in claimant's Green Form that are at issue, we must affirm the Trust's final determination and may grant such other relief as

deemed appropriate. See id. Rule 38(a). If, on the other hand, we determine that there is a reasonable medical basis for the answers, we must enter an Order directing the Trust to pay the claim in accordance with the Settlement Agreement. See id. Rule 38(b).

In support of her claim, Ms. Brown makes the same arguments she made in contest; namely, that she should prevail based upon the findings of the attesting physician, who attested that Ms. Brown suffered from moderate mitral regurgitation and a reduced ejection fraction in the range of 40% to 49%.

In response, the Trust asserts that claimant has failed to establish a reasonable medical basis for her claim by not responding to the findings of the auditing cardiologist. The Trust also argues that claimant failed to explain why Dr. Anwar's Green Form answers conflicted with the original findings he recorded in the report of claimant's echocardiogram.

After reviewing the entire Show Cause Record, we find claimant's arguments are without merit. First, and of crucial importance, Ms. Brown does not adequately challenge Dr. Soble's findings that claimant did not have moderate mitral regurgitation or a reduced ejection fraction. Despite an opportunity in the contest and show cause process to do so, claimant did not present any additional evidence in support of her claim. Instead, Ms. Brown rests only on Dr. Anwar's check-the-box diagnosis on her Green Form. Although claimant asserted an inability to obtain an opinion from another medical expert, claimant does not

explain why she did not at least contact her attesting physician to address the auditing cardiologist's conclusions.

Moreover, claimant did not provide any explanation for the discrepancies in Dr. Anwar's findings set forth in the report of claimant's echocardiogram and Dr. Anwar's responses in the Green Form. Notably, Dr. Anwar's findings on the report of claimant's echocardiogram (i.e., that claimant had "+1" mitral regurgitation and an ejection fraction greater than 60%) would not qualify claimant for Level II Matrix Benefits. See Settlement Agreement § IV.B.2.c.(2)(b).

Finally, claimant did not identify any particular error in the auditing cardiologist's findings. Mere disagreement with the auditing cardiologist without identification of specific errors by the auditing cardiologist is insufficient to meet a claimant's burden of proof. Ms. Brown, therefore, has failed to establish that there is a reasonable medical basis for her claim.

For the foregoing reasons, we conclude that claimant has not met her burden of proving that there is a reasonable medical basis for finding that she had moderate mitral regurgitation and a reduced ejection fraction. Therefore, we will affirm the Trust's denial of Ms. Brown's claim for Matrix Benefits.